

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
10 May 2001 (10.05.2001)

PCT

(10) International Publication Number  
WO 01/32262 A1

a n e

(51) International Patent Classification<sup>7</sup>: A61N 5/067

(21) International Application Number: PCT/CA00/01269

(22) International Filing Date: 27 October 2000 (27.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/162,787 1 November 1999 (01.11.1999) US

(71) Applicant and

(72) Inventor: PASSY, Philip, W. [CA/US]; 467 Yacht Club  
Road, Hartwell, GA 30643 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

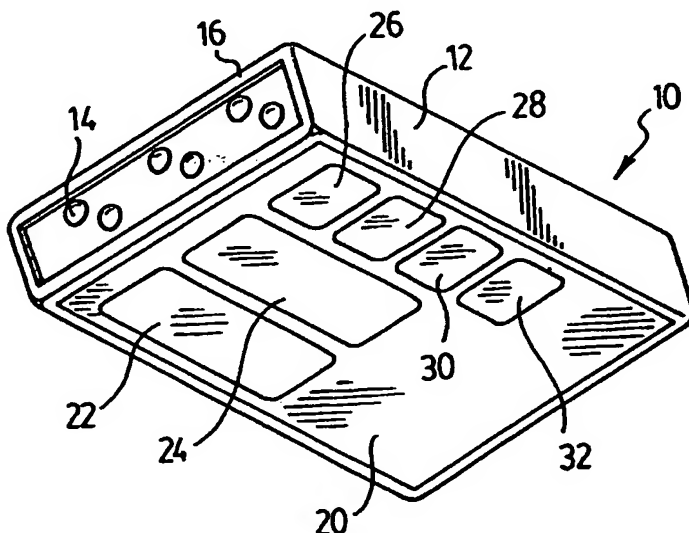
— With international search report.

(74) Agent: WOODLEY, John, H.; Sim & McBurney, 330  
University Avenue, 6th floor, Toronto, Ontario M5G 1R7  
(CA).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

4-10 LAS. Diode  
cluster  
mp  
single 2  
overlaid

(54) Title: MINIATURE CLUSTER LASER THERAPY DEVICE



(57) Abstract: The present invention is directed to a small portable laser therapy device that can easily be carried and applied to an affected area. The device comprises a casing; a plurality of laser diodes arranged in a cluster along the casing and a source of power to the diodes. The outside of the casing includes means for generating an input of selected power output of the laser diodes, means for generating an input of selected time the laser diodes are to be powered, and a processor to process the input of selected power output and the input of selected time and generate an output signal. A programmable logic device receives the output signal and controls the operation of the laser diodes.

WO 01/32262 A1

## MINIATURE CLUSTER LASER THERAPY DEVICE

### FIELD OF THE INVENTION

The present invention is directed to a small portable hand-held cluster  
5 laser device useful in the control of pain and tissue healing.

### BACKGROUND OF THE INVENTION

The therapeutic advantages of lasers have long been recognized.  
Lasers have been used in surgical and cosmetic applications as well as in the  
photodynamic therapy of cancer. Lasers have also been used to simulate the  
10 fine needles used in acupuncture therapy.

Lasers have also been used in the treatment of pain. For example, US  
Patent No. 5,640,978 describes a method for pain relief using low power laser  
light which is particularly adapted for treatment of chronic and referred pain  
such as chronic headaches and migraine headache as well as pain of the  
15 upper or lower back, neck and shoulders. The laser energy applied to the  
area is believed to increase lymphatic circulation at the site and to increase  
blood flow and cellular metabolism in the area which also promotes more  
rapid healing of lesions which cause the pain.

U.S. Patent No. 5,514,168 also describes a method of treating  
20 migraine headaches as well as atypical pain using bursts of low power (e.g. 2  
mW) from a helium neon laser having a maximum output of 5 mW and an  
application time of 20 to 30 seconds.

As mentioned above, lasers have also been used to promote wound  
healing. US Patent No. 5,021,452 discloses a process for improving wound  
25 healing which comprises irradiating the wound site with a low power laser.

US Patent No. 4,724,835 discloses a laser therapeutic device which is  
used to irradiate an area of cutaneous or subcutaneous physical injury and  
thereby produce healing and pain reduction.

Another method and apparatus for the use of a laser in the stimulation  
30 of biological processes related to cellular activity is disclosed in US Patent No.  
4,686,986. The invention is particularly relevant to the healing of lesions on a  
body surface, i.e wounds, ulcers and epithelial injuries.

US Patent No. 4,672,969 is also directed to a laser healing method. An  
Nd:YAG laser is used to heat biological tissue to a degree suitable for

denaturing the tissue proteins such that the collagenous elements of the tissue form a "biological glue" to immediately seal the tissue being treated.

United States Patent No. 5,616,140 is directed to a portable bandage *present* which can supply a patient with a pre-programmed laser therapy regimen.

- 5 Such a device is rather bulky and is not easily applied to provide temporary relief of symptoms. The device includes a combination of laser diodes and LED's.

- 10 Many laser treatment modalities depend on the thermal effects of the laser for their efficacy. A method for treating an area of biological tissue without damaging thermal effects is disclosed in US Patent No. 5,951,596. Treatment with either a Nd:YAG or Nd:YLF laser was found to reduce pain in soft tissues, reduce inflammation and enhance the healing of tissue by the stimulation of microcirculation.

- 15 Laser therapy has also been proposed for the treatment of human neurological problems. US Patent No. 4,671,285 discloses a method of treating disease or damage to the central nervous system by applying monochromatic light having a non-traumatic power density to the skin adjacent to a specific peripheral nerve region.

- 20 Although various types of laser therapy have been used for different conditions, some problems encountered with the prior art devices include the lengthy time required to achieve a therapeutic effect and the excessive heating of tissue during treatment. Also, most of the prior art devices necessitate the visit of the patient to a professional since the devices are not generally small, portable or easy to use.

- 25 The present invention takes advantage of very recent advances in the field of microelectronics to provide for a small, battery powered, cluster laser device that can easily be used by an individual in their own home, workplace, etc.

#### SUMMARY OF THE INVENTION

- 30 The present invention is directed to small hand-held cluster laser therapy device which is useful to treat pain and to enhance wound healing.

According to one aspect of the invention, there is provided a small portable laser therapy device comprising:

- i) a casing;

- ii) a plurality of laser diodes arranged in a cluster along one edge of the casing;
- iii) a source of power to the diodes;
- iii) means for generating an input of selected power output of the laser diodes;
- iv) means for generating an input of selected time the laser diodes are to be powered;
- v) a processor to process the input of selected power output and the input of selected time and generate an output signal; and
- vi) a programmable logic device to receive the output signal and control the operation of the laser diodes.

In a further aspect of the invention, there is provided a process for controlling the duration and intensity of laser therapy wherein a laser device having a processor, a programmable logic device, a laser driver and a power source is provided; a user enters variables of time and power required; the processor processes the variables and communicates with the programmable logic device to turn on a set of laser diodes; the programmable logic device controls the amount of power to the laser diodes and the processor communicates with the laser driver to control the time that the lasers are turned on.

In another aspect of the invention, a method of providing laser therapy is provided. The method comprises the steps of:

- i) providing a compact laser therapy device as described above;
- ii) selecting an appropriate time the laser diodes are to be powered;
- iii) selecting an appropriate power output for the laser diodes;
- iv) entering selected values into the processor; and
- v) applying the device to the affected area.

The time and power output levels may be selected by an end user or they may be pre-selected and entered by the manufacturer or therapist depending on the application for which the device is to be used. The device may optionally include a lock-out mechanism to prevent an end user from adjusting the variables.

In accordance with yet another aspect of the invention, there is provided a method of treating pain which comprises applying the cluster laser device to appropriate acupuncture sites.

#### BRIEF DESCRIPTION OF THE DRAWINGS

5 A preferred embodiment of this invention is illustrated in the accompanying drawings, in which like numerals denote like parts throughout, and in which:

Figure 1 is a perspective view of the device;

10 Figures 2A and 2B are schematics illustrating the multiplication of energy effect;

Figure 3 is a front view of the device illustrating the touch screen;

Figure 4 is an illustration of the device in use; and

Figure 5 is a circuit diagram of the device.

#### DETAILED DESCRIPTION OF THE INVENTION

15 The present invention is directed to a small, portable cluster laser device which can be used to alleviate pain and promote healing. The device can be used in a variety of milieus such as medical, physiotherapy, geriatric and acupuncture clinics as well as in the home or whilst mobile. The device is also useful in nursing homes and for veterinary applications.

20 Several dental procedures can also involve the use of the present invention. For example, the application of the device directly after tooth extraction helps prevent alveolitis. In other procedures such as caries therapy, endodontics, treatment of periodontal disease, odontological surgery, TMJ disease and the treatment of oral mucosa diseases, the laser therapy device  
25 of the present invention can be used to reduce pain and inflammation and to promote healing.

Previous laser devices are either large and bulky or utilize a single laser. The present invention is directed to the surprising result that a cluster of laser diodes can be provided in a compact, portable, programmable device.

30 Because the lasers are arranged in a cluster, the beams emitted by juxtaposed diodes overlap at the treatment surface providing a multiplicity of laser therapy. A microelectronic arrangement of components makes the present device possible.

Unlike the laser devices of the prior art, the present invention is very small, about the size of a pager telecommunications device, and can easily be carried in a pocket or attached to a belt. The device is usually battery powered and may be automatically rechargeable. The portable laser therapy device of the present invention can be utilized by both the medical professional and the individual in a broad range of applications. Other advantages of the present invention are that it is compact, hand-held and less costly than other types of laser devices.

Although small laser devices are known, these are single beam lasers and not a cluster of laser diodes and although some therapeutic effect has been claimed using other types of low power laser devices, the length of treatment time required is unacceptably long. Also, the devices of the prior art, while portable in some sense, are usually associated with a console which must be carried along to control the laser device. The cluster laser device of the present invention has the further advantage that the individual diodes are strategically positioned such that the emitted beams overlap resulting in a duplicate or triplicate effect. In this way, the cluster laser device is able to provide a therapeutic effect in a short period of time. In addition, because cold-powered laser diodes are used in the device there are none of the excessive thermal effects seen with other types of laser treatment devices.

In a preferred embodiment, as illustrated in Figure 1, the laser device 10 comprises a casing 12 which is small enough to render the device 10 easily portable. In a preferred embodiment, the size of the casing 12 does not exceed the proportions of 12cm x 7cm x 5cm. Of course, it is clearly apparent that other proportions and shapes could be used and the device would still maintain its portability.

In the preferred embodiment, a plurality of cold-powered laser diodes 14 are distributed along an upper surface 16 of the device 10. There are preferably four to ten diodes of 5 to 10 mW, each which emit at a wavelength within the range of 630 to 830 nanometres. In a preferred embodiment, the laser diodes emit at a wavelength of about 785 mW.

As shown in Figures 2A and 2B, the laser diodes 14 are arranged such that the emitted beams 16 intersect, thereby providing a multiplicity of photo-energy to the treatment site.

In one embodiment of the invention, the front face 18 of the device 10 comprises a touch screen or push membrane 20 which can be used to select the power level and time period for the treatment. In another embodiment, the power output and the time output may be preselected by the manufacturer or by a treatment specialist in accordance with the specific application for which the device is to be used. In this situation, the device may optionally be designed so as to prevent an end-user from adjusting the selected outputs. Various types of lock-out options are contemplated.

Figure 3 illustrates a preferred embodiment of a push membrane 20. A laser output panel 22, a time period panel 24, a stop button 26, a start button 28, a level selection button 30 and an enter button 32 are arranged on the membrane 20. Of course, it is clearly apparent to one skilled in the art that the positioning of the various panels and buttons is not limited to the front face.

To operate the device, a user selects a parameter by touching the laser output panel 22 or the time period button 24 and then uses the select button 30 to select the appropriate variable of laser output or time. Once the variable has been selected it is entered into the system using the enter button 32. The parameters which are selected are based either on established protocols for the treatment of specific conditions or a customized protocol derived for the user by a qualified practitioner. As illustrated in Figure 4, to perform the treatment at the desired variables of output and time, the user simply applies the device 10 to the area to be treated 34 and presses the start button 28. The device will automatically turn the laser diodes off at the end of the selected time period and signal to the user that the treatment is finished. Thus, the device can be easily operated by a non-professional as the only variables are power, time and on/off. Treatment times are usually short, with the greatest therapeutic effects being achieved in as little as 2 to 10 minutes.

As stated above, none of the prior art devices can compare in terms of flexibility, portability, safety, ease of operation and efficiency.

Referring now to Figure 5, a circuit diagram of the present invention is shown. The laser device 100 comprises a processor 102, a programmable logic device 104 and a laser driver 106. Power to the device is provided by a battery 112.

The processor 102 of the preferred embodiment is a ROM-based high-performance microcontroller (MCU). The processor 102 receives the variables from the user via the touch screen and processes the entered data. Once the user has pressed 'Enter' the data is processed by the processor 102. The processor 102 then communicates with the programmable logic device 104 to turn on a set of laser diodes 108. In the preferred embodiment, there are six diodes in the set of laser diodes 108. The programmable logic device 104 controls the power sent to the laser diodes 108. For instance, if the user requires only selects 50% laser output, the programmable logic device 104 provides 50% power to the laser diodes 108. The laser driver 106 controls all of the laser diodes within the laser device 100. In the preferred embodiment, there is only one laser driver 106 to control all of the diodes 108. Therefore, when a user selects 50% treatment, all of the laser diodes 108 are activated and running at half intensity.

Simultaneously, the processor 102 communicates with the laser driver 106 to time the treatment process. A clock 110 is connected to the processor 102 in order to time the treatment period. Once the treatment period has elapsed, the processor 102 communicates with the laser driver 106 to terminate the treatment and to turn off the laser diodes 108.

## EXAMPLES

The above disclosure generally describes the present invention. A more complete understanding can be obtained by reference to the following specific examples. These examples are described solely for the purposes of illustration and are not intended to limit the scope of the invention. Changes are contemplated as circumstances may suggest or render expedient.

### **Example 1. Use of the device in the treatment of Carpal Tunnel Syndrome.**

Carpal Tunnel Syndrome is caused by repetitive stress movements and is a debilitating condition. Laser therapy offers an effective alternative to other traditional techniques such as surgery. This condition is treated by first applying the laser device to the back and side of the neck. Then, the acupuncture points in the forearm muscles around the elbow joint are treated. Finally localized tender spots and acupuncture points within the wrist area are stimulated.



**Example 2. Treatment of Shingles (Herpes zoster)**

Shingles is a viral inflammation of the nerve root which causes a painful blistering rash appearing on the skin along the path of the final fibres of the nerve. There is intense neuralgic pain along the course of the nerve.

- 5 Treatment is initiated by using the laser device to provide phototherapy to the spine at the origin of the nerve root. Then each of the following points are irradiated for two minutes each until the pain subsides. The points are: above the inner border of the kneecap, below the inner knee joint, above the inner ankle bone, below the outside of the knee, hollow between outer ankle bone and
- 10 Achilles tendon, end of outer elbow, between thumb and index finger, outer side of the hand, top of foot at base of 2<sup>nd</sup> and 3<sup>rd</sup> toes, and halfway between the outside of the shoulder blade and the center of the spine.

- Although preferred embodiments of the invention have been described herein in detail, it will be understood by those skilled in the art that variations
- 15 may be made thereto without departing from the spirit of the invention or the scope of the amended claims.

I claim:

1. A small portable laser therapy device comprising:

- 5           i) a casing;  
          ii) a plurality of laser diodes arranged in a cluster along the  
          casing;  
          iii) a source of power to the diodes;  
          iii) means for generating an input of selected power output for  
          the laser diodes;  
          iv) means for generating an input of selected time the laser  
10          diodes are to be powered;  
          v) a processor for processing the input of selected power output  
          and the input of selected time and generate an output signal;  
          and  
          vi) a programmable logic device to receive the output signal and  
15          control the operation of the laser diodes.

2. The laser therapy device of claim 1, wherein said plurality of laser diodes  
are arranged in sufficient proximity to each other such that laser light emitted  
from juxtaposed laser diodes overlaps at a treatment site.

20          3. The laser therapy device of claim 1, wherein said plurality of laser diodes  
comprises 4 to 10 laser diodes distributed along an upper surface of said  
casing.

25          4. The laser therapy device of claim 1, wherein said plurality of laser diodes  
comprises laser diodes of 5 to 10 mW each.

5. The device of claim 4 wherein each of said laser diodes emits at a  
wavelength between 630 and 830 nanometres.

30          6. The laser therapy device of claim 1 wherein at least one of said input of  
selected power output and said input of selected time are preselected by a  
manufacturer or therapist and are non-changeable by a user.

7. The laser therapy device of claim 1 wherein said means for generating an input of selected power output and said means for generating an input of selected time comprises a user-accessible touch screen or push membrane.

5 8. The laser therapy device of claim 1, wherein the processor is a ROM-based high performance microcontroller.

9. The laser therapy device of claim 1, wherein said source of energy is a battery.

10

10. A process for controlling the duration and intensity of laser therapy wherein a laser device having a processor, a programmable logic device, a laser driver and a power source is provided; a user enters variables of time and power required; the processor processes said variables and  
15 communicates with the programmable logic device to turn on a set of laser diodes; the programmable logic device controls the amount of power to the laser diodes and the processor communicates with the laser driver to control the time that the lasers are turned on.

20 11. The process according to claim 9, wherein a single laser driver controls a plurality of laser diodes whereby each of said plurality of laser diodes runs at a constant pre-selected intensity.

12. A method of providing laser therapy comprising:

- 25
- i) providing a compact laser therapy device according to claim 1;
  - ii) selecting an appropriate time the laser diodes are to be powered;
  - iii) selecting an appropriate power output for the laser diodes;
  - iv) entering selected values into the processor; and
  - v) applying the device to the affected area.

30

13. A method of treating pain which comprises applying the laser therapy device of claim 1 to appropriate acupuncture sites.

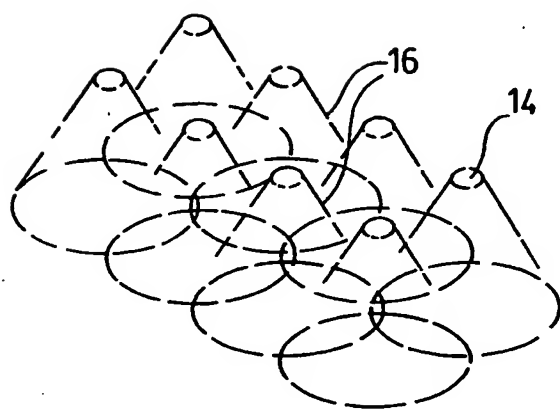
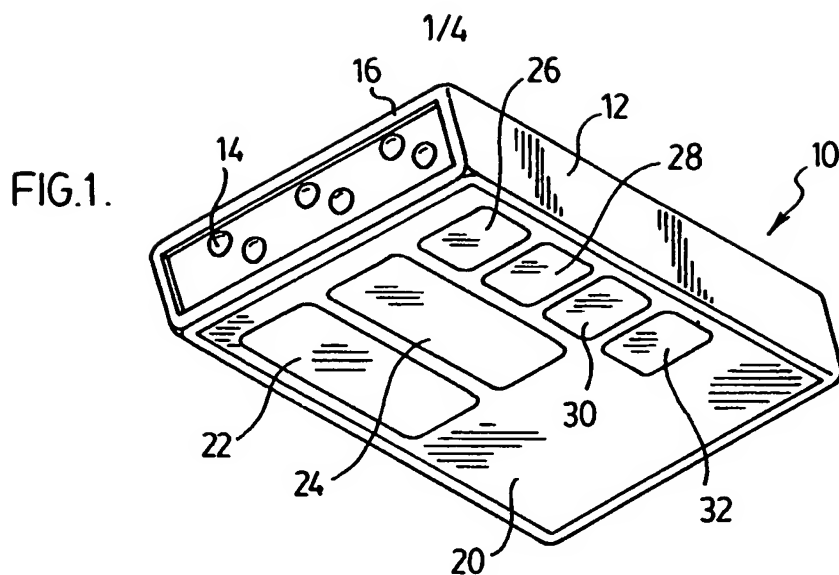


FIG.2A.

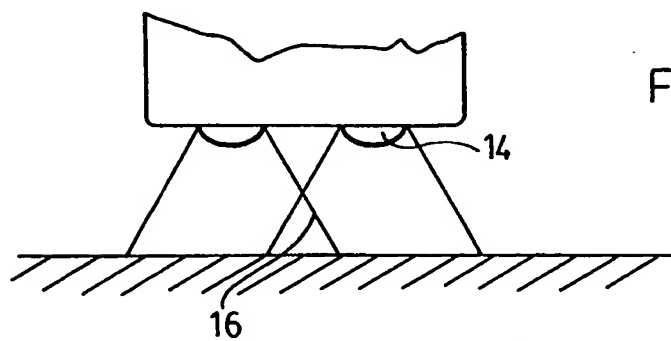
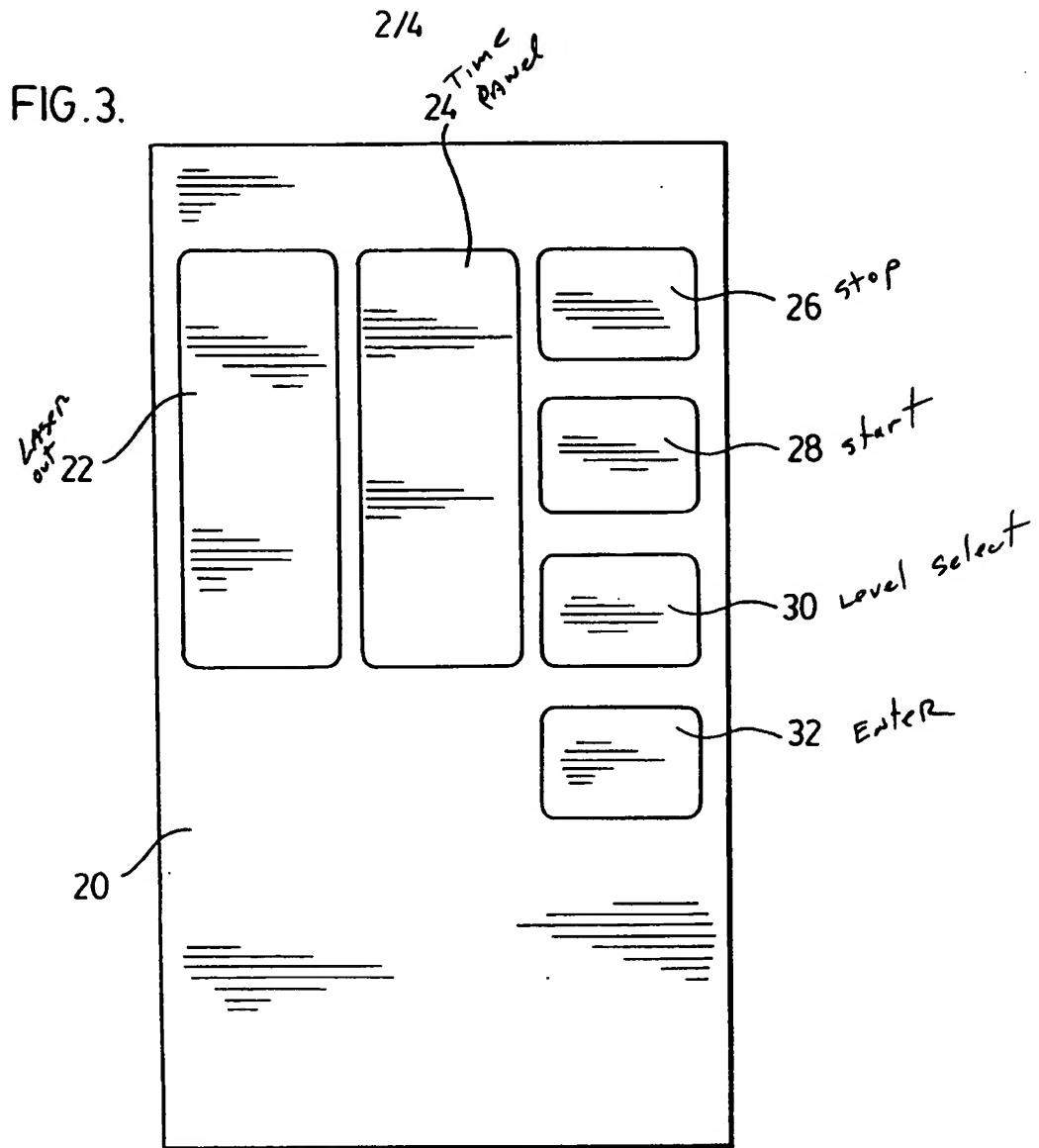


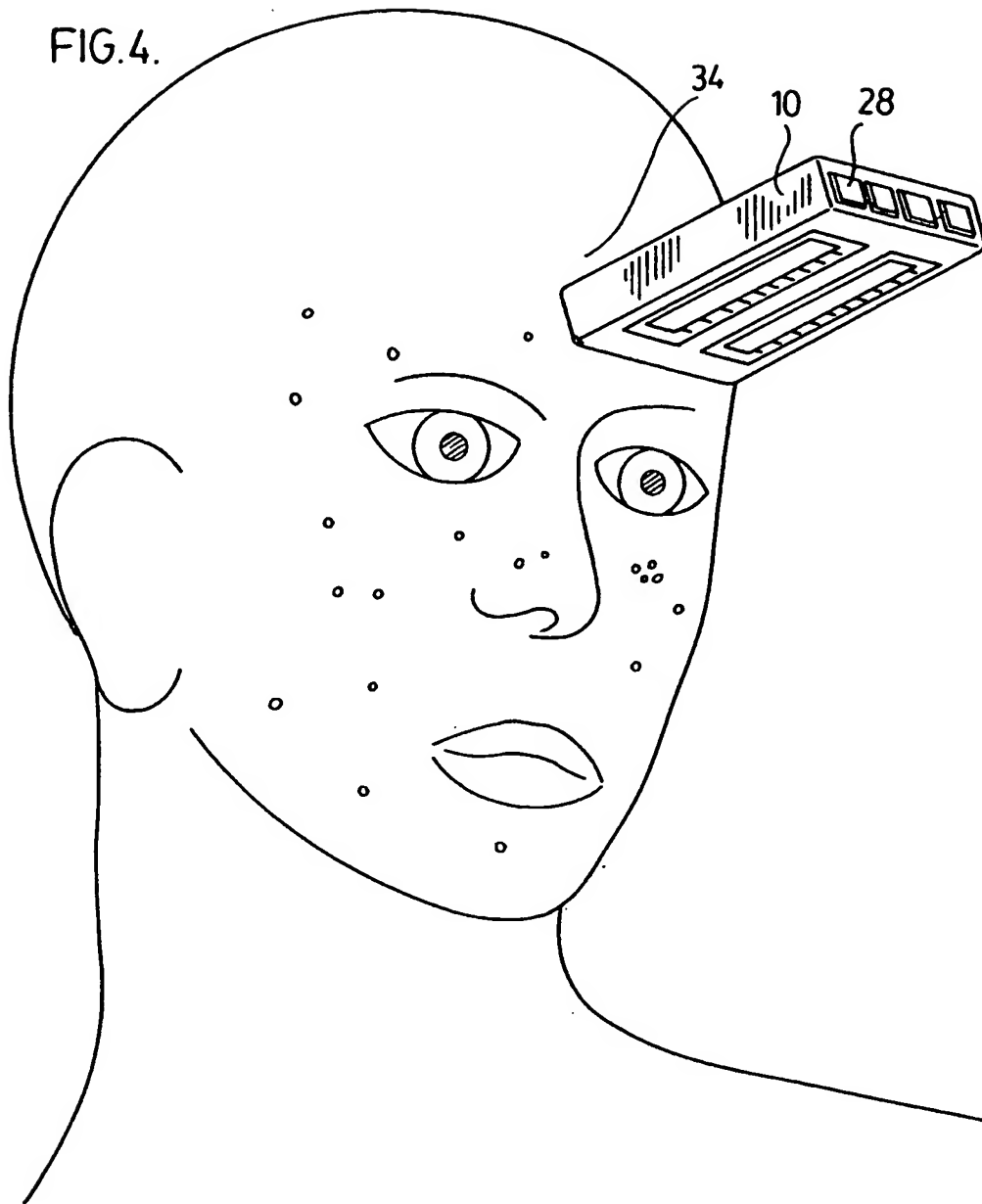
FIG.2B.

SUBSTITUTE SHEET (RULE 26)



3/4

FIG. 4.



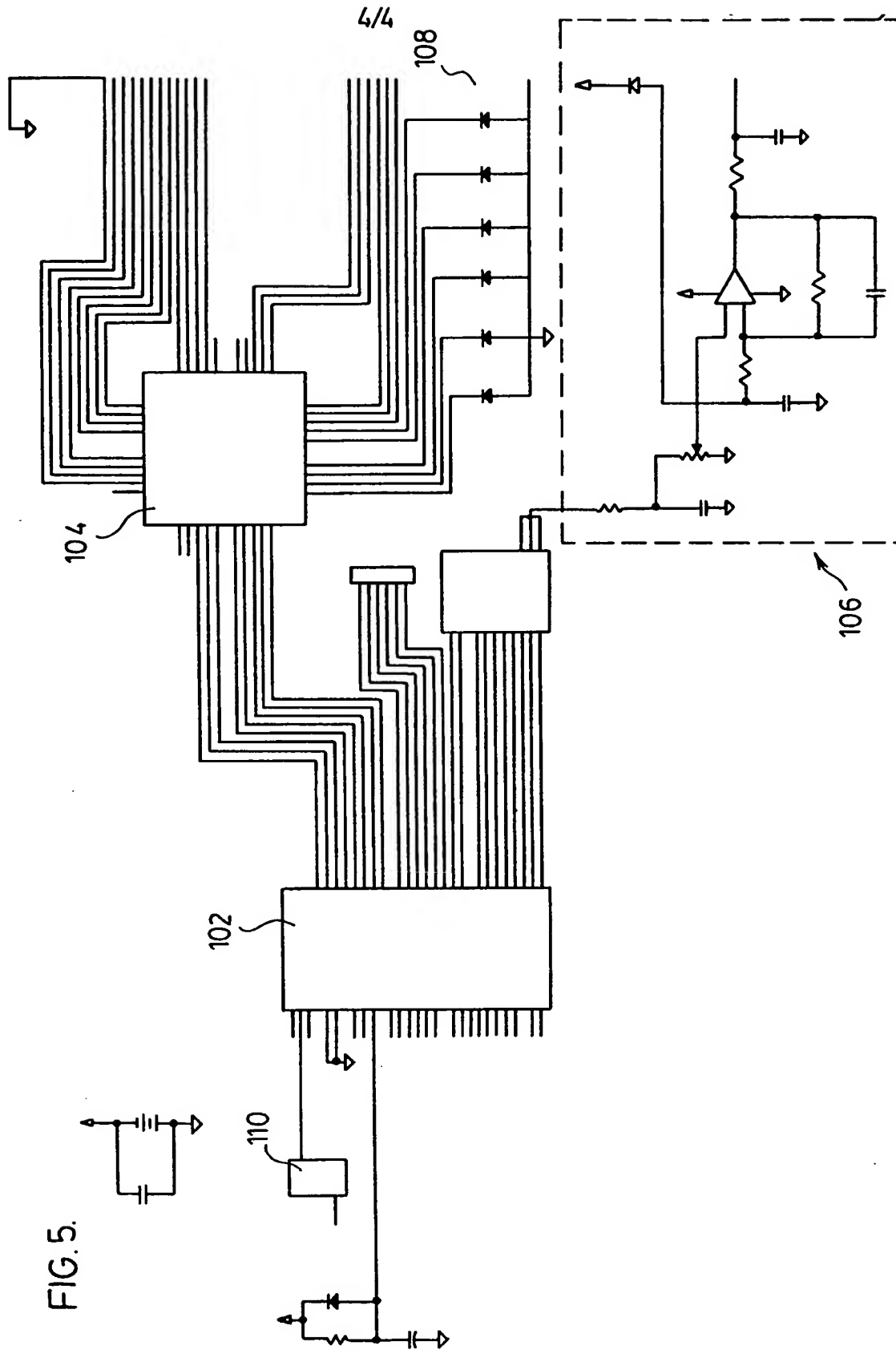


FIG. 5.

# INTERNATIONAL SEARCH REPORT

Internat Application No

PCT/CA 00/01269

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61N5/067

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 42178 A (LASER RESEARCH INTERNATIONAL I ;PASSY PHILIP W (US)) 26 August 1999 (1999-08-26) page 4, line 28 -page 5, line 9	1-9
X	WO 98 20937 A (CAMPBELL IAIN ;KAHN FRED (CA); MEDITECH INTERNATIONAL INC (CA); ST) 22 May 1998 (1998-05-22) page 4, line 4 -page 5, line 1 page 20, line 9 -page 22, line 3	1-9
X	US 5 616 140 A (PRESCOTT MARVIN) 1 April 1997 (1997-04-01) cited in the application column 4, line 48 -column 5, line 10 column 6, line 37 -column 7, line 20 -/-	1-9



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

11 January 2001

Date of mailing of the international search report

17/01/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Petter, E



# INTERNATIONAL SEARCH REPORT

Internat: Application No

PCT/CA 00/01269

## C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 297 03 960 U (ENGELHARDT KLAUS DR ;POPP PETER (DE)) 7 May 1997 (1997-05-07) claims 1-10	1-5,9
A	US 5 549 660 A (IRON GIDEON ET AL) 27 August 1996 (1996-08-27) column 2, line 34 - line 56; figure 3	1-9
A	DE 198 32 904 A (MICHELS HEINZ ;MICHELS ILSE (DE)) 28 January 1999 (1999-01-28) column 2, line 20 - line 58	1-9

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati. Application No

PCT/CA 00/01269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9942178 A	26-08-1999	AU 2606399 A	06-09-1999
WO 9820937 A	22-05-1998	AU 4938897 A	03-06-1998
		BR 9712948 A	28-03-2000
		CA 2210450 A	13-05-1998
		EP 0951314 A	27-10-1999
US 5616140 A	01-04-1997	AU 2104195 A	09-10-1995
		US 6156028 A	05-12-2000
		WO 9525563 A	28-09-1995
		US 5989245 A	23-11-1999
DE 29703960 U	07-05-1997	NONE	
US 5549660 A	27-08-1996	US 5259380 A	09-11-1993
		JP 7100219 A	18-04-1995
		US 5500009 A	19-03-1996
DE 19832904 A	28-01-1999	DE 29713360 U	26-11-1998